The Cost Benefits of a Lean Six Sigma-Based Continuous Improvement Approach

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The COVID-19 pandemic has created far more than just a health crisis. The impact of government-mandated shutdowns, restricted travel and unpredictable demand has increased costs and created imbalance among supply chains and their end markets. This impact is particularly significant in medical manufacturing, where regulatory practices limit the ability to rapidly change component supply sources or processes beyond what has been validated or approved.

Reducing cost or increasing throughput to better address the impact of COVID-related supply chain disruption requires a measured approach which considers both immediate improvements and longer term options. Lean Six Sigma provides manufacturing teams with the training, tools and process to achieve these goals.

Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems has been applying Lean Six Sigma philosophy over the last year to address COVD-related challenges in its programs.

Six Sigma Green Belt training is in place in all its facilities, creating teams with enhanced problem solving skills to lead continuous improvement focus in each facility. The core tools used to drive this process include:

- 7S Workplace Organization
- Poka Yoke mistake proofing technique
- 8D systematic approach problem solving methodology
- Risk management & Process Failure Modes and Effects Analysis (PFMEA)
- Statistical process control.

The teams start by developing a project charter which defines the problem statement, clear business objectives and benefits drivers. A Gemba workshop is then conducted with participation from various functions to identify potential areas of improvement, together with a time study to pinpoint bottlenecks. In Lean philosophy, Gemba means the place where value is created, and the technique is derived from the Toyota Production System. A more commonly recognized corollary in the management world would be Tom Peters' concept of "management by walking around." The Green Belt teams learn from observing the process and talking with production operators about their perspectives. Following Gemba, a focused DMAIC (Define, Measure, Analyze, Improve, Control) methodology is used to initiate the improvement process.

A DMAIC spreadsheet is used to capture information in a concise form. The benefit of this approach is that each identified improvement opportunity is thoroughly analyzed and tested to ensure root causes are correctly identified and the magnitude of the improvement benefit of implementing the corrective action is thoroughly understood.

For example, in a DMAIC activity last year, the team identified potential improvements designed to improve throughput and lower cost on a project. Recent demand spikes had driven a need to switch to air shipment. The team's goal was to implement improvements that lowered overall project cost and also improved throughput to the point where surges in demand could be accommodated within the regular sea shipment schedule.

In performing DMAIC-related evaluations, teams review the overall production process to determine if any issues can be identified that are related to the 7 Lean Wastes:

- Defects
  - Parts not complying with customer specifications
  - Incorrect parts used or work instructions not followed
- Overproduction
  - Producing more than what is needed
  - Inaccurate forecast and demand or overstaffing
  - Unacceptable levels of finished goods inventory in warehouse
- Waiting
  - Products waiting for upstream processes to complete
  - Waiting related to lack of material, people, tool or information
  - Process bottlenecks or unexpected downtime
- Non-Utilized Talent
  - Undertrained resources or idle machines
- Transportation
  - Unnecessary movement of product or material
  - Inefficient production layout or material not within reach of production operators
- Inventory
  - Excess material that is not being processed
  - Overstocked or expired material
  - Excess work-in-process
- Motion
  - Unnecessary movement of people
  - People searching for materials or tools to complete the task
- Extra processing
  - Doing work that does not add value to the product
  - Unclear specification or quality standards
  - Overspecification driving inspection/rejection activity not related to critical-to-quality (CTQ) attributes.

They plotted a scattergram over two axes focused on opportunity impact and the effort associated with corrective action. That activity identified four opportunities with some impact and marginal effort. There were another three opportunities that offered greater impact at slightly higher effort and three opportunities that offered similar impact at a much higher effort.

The team then created a current state process map that mapped the production process flow, personnel, cycle time and takt time. They modeled a re-layout of the line for continuous flow vs a work cell arrangement. They then focused their efforts on two steps in the process: packaging the product in

a tray and final sealing operation. The workstations were then laid out to enable operators to work with components more efficiently in a smaller space by utilizing stackable, color-coded bins to store raw material. Small changes were made to housekeeping and cleaning tools to eliminate dust particles not already eliminated by cleanroom filtration and production attire, reducing the time operators needed to spend cleaning each product during the packaging stage. From a throughput standpoint, the best opportunity for improvement was redesigning the automated sealing machine's sealing plate to have six cavities on each side instead of four. They also worked with the equipment manufacturer to develop a process that utilized both sides of sealing plate, instead of just a single side. The specification for the outer tray was also reviewed with the customer to better identify which visual defects should signal a rejected product. Discussions were also held with the tray supplier to minimize the opportunity for handling or shipping related cosmetic defects.

The result was a 50 percent improvement in throughput and a reduction in the need for air shipments.

Lean Six Sigma provides well-trained teams with a focused process and core tools for evaluating and prioritizing improvement opportunities. Even the best planned projects can have room for improvement when production requirements increase significantly. In the current environment of increasing cost and imbalance between supply and demand, Lean Six Sigma provides Forefront Medical's team with the resources to help mitigate increasing costs while increasing throughput and process yield.

About Forefront Medical Technology

Forefront Medical Technology is a global medical device contract manufacturer with five locations. Singapore is Forefront's headquarters, as well as home to our Design Engineering Center and specialty manufacturing. JiangSu and Xiamen, China, are additional manufacturing locations and are also China FDA Registered. Shanghai, China and Farmington, CT USA are regional Business Development offices which assure our technical sales teams are close to our customers for local, responsive assistance.

We have developed extensive capabilities with laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding catheters, infusion sets, wire reinforced tubes, optically clear components, patient monitoring devices, electromechanical devices and other specialty products. Each of our locations has state of the art manufacturing capabilities that include class 100K clean rooms for extrusion and injection molding, complemented by class 10K clean rooms for assembly.

Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485:2016 and FDA Registered. Forefront is a wholly owned subsidiary of VicPlas International Ltd, who is listed on the SGX Main Board, Singapore stock exchange.

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